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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,609	11/30/1999	HELLE WEIBEL	5739.200-US	7926
23650	7590	01/26/2006	EXAMINER	
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/450,609

Applicant(s)

WEIBEL ET AL.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6,7,9,11-13,16 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6,7,9,11-13,16 and 28 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2005 has been entered.

### **Action Summary**

The rejection of claims 6, 7, 9, 11, 12, 13, 16, and 28 under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (WO 9741097) is being maintained for the reasons stated in the previous office Action.

The objection of Claims 29-31 is maintained for the reasons stated in the pervious office Action.

### **Response to Arguments**

Applicants' arguments filed November 4, 2005 have been fully considered but they are not persuasive. Applicants argue that the inventors of the present application discovered that when they use excipients which have low water content, the active

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ingredient and its salts do not decompose in the presence of and in contact with water and that Applicants have conducted various tests (Declaration of Thyge Borup Hjorth dated August 21, 2002) to compare the excipients used in the present invention and those used in the Lohray reference. This is not persuasive because the Declaration comprising comparison data has been carefully reviewed and considered but it is persuasive to the extent that employment of Avicel PH 112 of formulation B and D are more stable compared to Avicel PH 102 formulation A and D. However, Avicel PH 112 and Avicel PH 102 are both microcrystalline cellulose in general taught by Lohray and that it is the Examiner's position that the claimed invention is encompassed by the prior art since the low moisture contents within the microcrystalline is not specified.

Applicants' broad claims are not commensurate in scope with the breadth of the claims.

It is well established that a showing of unexpected results generally must be commensurate in scope with the breadth of the claims sought to be patented. See, inter

alia, (1) In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978)

(showing of unexpected results must be commensurate in scope with breadth of claim);

(2) In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990) (same);

and (3) In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (same).

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of 12/31/2003 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 9, 11, 12, 13, 16, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (WO 9741097).

Lohray et al. teaches at page 35, example, applicants' composition in a tablet form. Lohray et al. at page 34, lines 27-29, page 35, example, and page 7, lines 13-14, teach pharmaceutical composition containing applicants' active agent in tablet, capsule, or powder form, in combination with the pharmaceutically acceptable excipient set forth in claim 6, and flavourants, sweeteners set forth in claim 16, and other media normally employed in preparing such compositions. Lohray et al. teach that the above composition typically contains from 1 to 20% by weight of active compound, and the remainder of the composition being pharmaceutically acceptable carrier, diluents or solvents. (page 35, lines 1-3).

Lohray et al. do not expressly teach the low water content comprising anhydrous lactose and specific cellulose set forth in claim 6 and proportions of excipients set forth in claim 9.

It would have been obvious to one of ordinary skill in the art to modify Lohray composition to employ any form of lactose (e.g. anhydrous lactose) because Lohray et al. teach the composition comprising lactose in general. One would have been motivated to employ any form of lactose as taught by Lohray to provide a pharmaceutical composition containing the active agent for the effective treatment of diabetics because lactose as utilized in Lohray composition encompasses any lactose form including anhydrous lactose as claimed by the Applicants. The proportions of active agents to be used set forth in claim 9 and specified cellulose set forth in claim 6 are deemed obvious because it is within the knowledge of the skilled pharmacologist to optimize the range of amounts of active agents and the excipients to be utilized. Moreover, Lohray et al. teach the ranges of 1-20% as being an active compound and the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents. One of ordinary skill in the art would optimize this range of excipients within the range of about 20-80% as taught by Lohray et al. Further, Lohray et al. utilize one of cellulose derivative (e.g. carboxymethyl cellulose) as useful excipient and have a viable utility as an excipient which is so closely related to microcrystalline cellulose utilized claimed by the Applicants and it is to be chemically obvious therefrom (cellulose derivatives) in the absence of any unobvious or unexpected properties especially since one of ordinary skill in the art would expect that compounds so closely related chemically would have the same or essentially the same properties.

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For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Claims 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

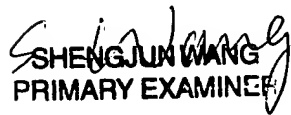
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Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

Jmk  
January 12, 2006

  
SHENGJUN WANG  
PRIMARY EXAMINER